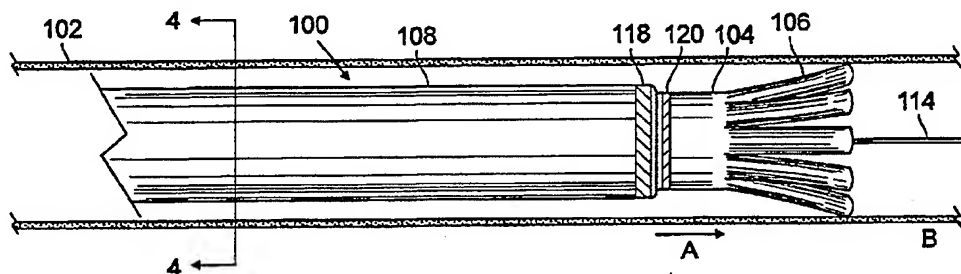




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(71) Applicant: INTERVENTIONAL INNOVATIONS CORPORATION [US/US]; 2670 Patton Road, St. Paul, MN 55113 (US).			
(72) Inventors: CLARK, David, W.; 9225 LaRivier Court, Eden Prairie, MN 55347 (US). CLARK, Souise, S.; 9225 LaRivier Court, Eden Prairie, MN 55347 (US). FORMAN, Michael, R.; 2026 Pinehurst Avenue, St. Paul, MN 55116 (US).			
(74) Agent: SKLAR, Brandon, N.; Brooks Haidt Haffner & Delahunty, 99 Park Avenue, New York, NY 10016 (US).			

(54) Title: DRUG DELIVERY CATHETERS AND METHODS OF USE



## (57) Abstract

A catheter (100) for delivering drugs or other agents is disclosed particularly suited for delivering drugs proximate the walls of a vessel, such as an artery or vein (102). The catheter comprises a shaft (104) with a distal portion comprising at least one and preferably a plurality of delivery members (106). When deployed, the delivery members flare from the catheter shaft at an acute or obtuse angle. At least a portion of the delivery members are within a restraining means such as a sleeve (108) or thread, for example, to maintain the delivery member within the diameter of the shaft prior to deployment. Delivery lumens (110) provide drugs to ports (112) in the delivery members (106) for delivery out of the catheter. The delivery members preferably bear against the wall of the vessel when deployed, to deliver drugs proximate the walls of the vessel, where blood flow is slow.

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## DRUG DELIVERY CATHETERS AND METHODS OF USE

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### Field of the Invention

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A drug delivery catheter and, more particularly, a drug delivery catheter with a self-expanding drug delivery portion which delivers drugs or other agents proximate the walls of a lumen or vessel, such as an artery or vein, and methods of its use.

### Background of the Invention

15

It is often necessary to deliver drugs to a particular site within a body. For example, catheters are used to deliver drugs or other agents to lumens or vessels within the cardiovascular system, the urethra, bladder, prostate, rectum and central nervous system, such as the spinal cord.

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In cardiovascular applications, for example, various types of agents are being investigated for use in preventing restenosis of an artery after percutaneous transluminal coronary angioplasty (PTCA) or percutaneous transluminal angioplasty (PTA). Heparin, an anticoagulant and inhibitor of arterial smooth muscle proliferation, is one such drug. Dexamethasone may also prevent smooth muscle proliferation. Integralin, an antiplatelet agent, can also be useful to prevent restenosis. See, for example, "Use of a Monoclonal Antibody Directed Against the Platelet Glycoprotein IIb/IIIa Receptor in High-Risk Coronary Angioplasty," Califf, Dr. Robert M., The New England Journal of Medicine, April 7, 1974, p. 956. Other drugs and agents are being investigated for efficacy, as well. Such drugs can be delivered before or after the angioplasty procedure. The delivery of lytic agents such as urokinase, streptokinase and recombinant tissue type plasminogen activator (rTPA), to dissolve plaque or a thrombosis in arteries and veins is also being investigated. Integralin may be efficacious, as well.

Because of blood flow through the artery, drugs delivered to the site of an angioplasty procedure, for

1 example, can be rapidly dissipated and removed from the  
delivery site before they can be absorbed in sufficient  
quantities to become effective. Catheters have therefore  
been developed to directly deliver drugs to the desired site  
5 and maintain them there. For example, U.S. Patent No.  
5,087,244 to Wolinsky et al., discloses a catheter with a  
flexible balloon having a plurality of minute openings. The  
balloon can be inflated by heparin. As the walls of the  
balloon contacts the arterial wall, the heparin exits the  
10 balloon, directly onto the walls. While enabling drug  
delivery directly to the desired site, the inflation of the  
balloon can damage the arterial wall, promoting restenosis.  
The balloon can also block the perfusion of blood distal to  
the delivery site, depriving tissue of needed blood. This  
15 limits the amount of time available for drug delivery. In  
addition, since the balloon is inflated by the heparin,  
heparin can leak out before the arterial wall is contacted,  
wasting the drug. The balloon also needs to be deflated  
prior to removal or to allow blood flow. The pressure  
20 required to deflate the balloon could draw blood into the  
balloon, preventing further use of the catheter until the  
blood has been removed.

U.S. Patent No. 4,824,436, also to Wolinsky,  
discloses a drug delivery catheter comprising a pair of  
25 occlusion balloons for securing the catheter in position and  
isolating a region of the artery which has been opened by  
PTCA, and a drug delivery conduit for delivering heparin  
under pressure into the region isolated by the occlusion  
balloons. The pressure of the heparin forces the heparin to  
30 coat to and penetrate the arterial tissue. This  
configuration presents the similar perfusion problems to  
those discussed above. The heparin, therefore, is only  
delivered for 5-60 seconds, which may be inadequate for  
sufficient absorption.

35 In U.S. Patent No. 4,636,195, Wolinsky discloses a  
similar catheter for delivering a solubilizing solution for  
dissolving plaque blocking an artery. This patent also  
relies on the pressure of drug delivery to force the  
solution into the plaque. A third balloon can also be

1 provided between the two occlusion balloons to compress the  
plaque and force the solubilizing solution into it. The  
solution can be delivered at a low pressure and absorb  
passively, as well.

5 The use of sufficient pressures to drive the drug  
into the tissue or plaque may damage the arterial wall.  
Passive delivery is slow and may not enable sufficient  
absorption of the medication. Passive delivery can be  
particularly inappropriate for drug delivery in an artery  
10 because of the limited time blood flow can be stopped.

U.S. Patent No. 5,336,170 to Kaplan et al.,  
discloses a catheter with drug delivery ribs which are  
brought into contact with the walls of the body lumen by an  
inflatable balloon. A series of ports in the catheter shaft  
15 can be provided proximal to the balloon, to allow for  
perfusion of blood through the catheter shaft. As above,  
the amount of blood which can be perfused is limited.  
Inflation of the balloon can also damage the wall of the  
lumen.

20 One commercially available drug delivery product is  
the DISPATCH® from Scimed®. The DISPATCH® includes an  
inflatable polyurethane coil which provides a path for blood  
to flow and defines regions proximate the wall of the vessel  
into which drug is delivered. While apparently allowing for  
25 significant perfusion, the device is complex and difficult  
to use and manufacture. The inflatable coil can also  
prevent portions of the artery from being exposed to the  
drug.

Active perfusion, such as the injection of  
30 perfluorochemicals or blood through the guide wire lumen, is  
also used.

It is known that the velocity of fluid flow through  
a tube varies across the axial cross-section of the tube.  
The velocity is maximum at the center of the tube and  
35 approaches zero at the walls. In an artery or a vein, blood  
flow is very slow in the region proximate the walls. If  
drugs or other agents could be effectively delivered  
proximate the walls, the blood or other fluid flow can  
atraumatically carry the delivered drug or agent over the

1 site of interest. The delivered drug or agent would also  
not dissipate as rapidly as drug delivered at the center of  
the vessel. Less drug could then need to be delivered,  
shortening procedures and decreasing their cost.

5 A drug delivery device which could deliver drugs  
proximate the walls of the vessel without blocking blood  
flow, would be advantageous.

#### Summary of the Invention

10 A catheter is disclosed comprising self-expandable  
delivery members which are compressed while the catheter is  
advanced to a site within a lumen, such as an artery or a  
vein, for example. When released at a desired site, the  
delivery members flare toward the wall of the lumen to  
deliver drugs or other agents proximate the wall.

15 In accordance with one embodiment of the invention,  
a catheter is disclosed comprising a delivery portion  
comprising a shaft, at least one resilient delivery member  
at the distal portion of the shaft, and at least one  
delivery lumen extending longitudinally through the shaft  
20 and delivery member. The delivery member includes at least  
one delivery port in fluid communication with the delivery  
lumen. The delivery member is capable of extending from the  
shaft at an angle with respect to a longitudinal axis  
through the catheter shaft. A means for compressing the  
25 delivery member is also provided, wherein when the means for  
compressing is removed from the delivery members, the  
delivery members flare to the angle with respect to the  
catheter shaft.

30 In accordance with another embodiment of the  
invention, a catheter is disclosed comprising a shaft having  
distal and proximal portions, and a sleeve, wherein the  
shaft is received within the sleeve and the shaft and sleeve  
are adapted to be moved with respect to each other. The  
shaft comprises a plurality of resilient delivery members  
35 extending from the distal portion of the catheter shaft at  
an acute angle with respect to a longitudinal axis of the  
catheter shaft when the sleeve is retracted from the distal  
portion. The delivery members are compressed by the sleeve  
when the distal portion of the shaft is received within the

1 sleeve. A plurality of delivery lumens corresponding to the number of delivery members extend through the catheter shaft and delivery members. At least one delivery port is provided in each delivery member.

5 A catheter is also disclosed comprising a shaft having distal and proximal portions, and a sleeve, wherein the shaft is received within the sleeve and the sleeve and shaft can move with respect to each other. The shaft comprises a plurality of resilient delivery members flaring from the distal portion of the shaft at an acute angle with respect to a longitudinal axis of the catheter shaft when the sleeve is retracted from the distal portion. The delivery members comprise a first, tapered portion having a distal end and extending at the angle with respect to the longitudinal axis of the catheter shaft, and a second, essentially longitudinal portion depending from the distal end of first portion. A plurality of delivery lumens corresponding to the number of delivery members extend through the shaft and delivery members. At least one delivery port is provided in each delivery member.

20 A catheter is also disclosed comprising a shaft having distal and proximal portions, and a sleeve, wherein the catheter shaft is received within the sleeve and the sleeve and shaft can move with respect to each other. The shaft comprises a plurality of resilient delivery members having a first portion with a distal end extending rearwardly from the distal portion of the shaft when the sleeve is retracted from the distal portion. The shaft further comprising a plurality of delivery lumens extending through the shaft and the delivery members.

30 A catheter is also disclosed wherein the delivery members are compressed by a thread. When the thread is removed, the delivery members flare from the catheter shaft at an angle with respect to a longitudinal axis of the catheter shaft.

35 In all the above embodiments, the delivery members are preferably adapted to bear against the wall of a lumen when released at a site. Different drugs or other agents can be delivered through different lumens.

1           A method of delivering drugs or other agents to a  
lumen is also disclosed comprising advancing a catheter  
having compressed delivery members, releasing the delivery  
5 members, and delivering drugs or other agents through the  
catheter and delivery members.

          A method of treating thrombosis is also disclosed  
comprising advancing a first catheter with compressed  
delivery members proximal to a thrombus, advancing a second  
catheter with compressed delivery members through the  
10 thrombus, releasing the delivery members of the first  
catheter, releasing the delivery members of the second  
catheter, delivering drugs or other agents through the first  
catheter, and delivering drugs or other agents through the  
second catheter.

15           A method is also disclosed comprising advancing a  
distal portion of a catheter having compressed expandable  
solid members through a thrombus, releasing the solid  
members to extend rearwardly from a distal end of the  
catheter, and removing the thrombus by retracting the  
20 catheter into a guide catheter, for example.

#### Description of the Figures

Fig. 1 is a side view of a drug delivery catheter in  
accordance with a first embodiment of the invention in its  
deployed position within a lumen, such as an artery;

25           Fig. 2 is a partial cross-sectional view of the  
catheter of Fig. 1, with a sleeve partially cut away to  
reveal the distal portion of the shaft, when the catheter is  
in a non-deployed position;

30           Fig. 3 is a cross-sectional view of the catheter of  
Fig. 1;

Fig. 4 is a cross-sectional view of the catheter of  
Fig. 1, through line 4-4 of Fig. 1;

Fig. 5 is a cross-sectional view of the proximal  
portion of the catheter of Fig. 1;

35           Fig. 6 is a cross-sectional view of the catheter of  
Fig. 1, wherein a thread compresses the delivery members;

Fig. 7 is a cross-sectional view of the catheter of  
Fig. 1, wherein the thread extends through a guide wire  
lumen;



1           Fig. 8 is a cross-sectional view of the catheter of  
Fig. 1, wherein the thread extends through a delivery lumen;

          Figs 9A-9E illustrate the formation of a releasable  
knot for use with the embodiments of Figs. 6-8;

5           Fig. 10 is a side view of a catheter of a second  
embodiment of the present invention, in its deployed  
position within a lumen;

          Fig. 11 is a cross-sectional view of the catheter of  
Fig. 10;

10           Figs. 12-13 illustrate steps in the manufacture of  
the catheters of Figs. 1 and 10;

          Figs. 14-15 illustrate further steps in the  
manufacture of the catheter of Fig. 10;

15           Fig. 16 is a side view of another embodiment of the  
present invention, deployed within a vein, for example;

          Fig. 17 is a cross-sectional view of the catheter of  
Fig. 16;

          Fig. 18 is a cross-sectional view of the catheter of  
Fig. 16, through line 18-18;

20           Fig. 19 is a partial cross-sectional view of the  
catheter of Fig. 16, with a portion of the sleeve in cross-  
section to reveal the distal portion of the shaft;

          Figs. 20-23 illustrate steps in the manufacture of  
the catheter of Fig. 16;

25           Fig. 24 is a side view of a fourth embodiment of a  
catheter in its deployed position within a lumen such as the  
vena cava;

          Fig. 25 is a cross-sectional view of the catheter of  
Fig. 24;

30           Fig. 26 is a partial cross-sectional view of the  
catheter of Fig. 24 in its compressed position, wherein the  
sleeve is partially cut away to reveal the distal portion of  
the shaft;

35           Fig. 27 is a side view of a tool used in the  
manufacture of the catheter of Fig. 25; and

          Fig. 28 is a cross-sectional view of the tool of  
Fig. 27, in position during the manufacture of the catheter  
of Fig. 25.

1

### Description of the Invention

Fig. 1 is a side view of a catheter 100 in accordance with one embodiment of the present invention, deployed to deliver drugs or other agents in a lumen or vessel, such as an artery 102. The catheter comprises a shaft 104 with a distal portion comprising one or more resilient delivery members 106 which flare from the shaft at an acute angle, towards the walls of the artery 102. Eight delivery members 106 are provided in this embodiment, five of which are shown in Fig. 1. The three additional delivery members, obscured in the view of Fig. 1, are shown in Fig. 2.

Fig. 2 is a view of the catheter 100 of Fig. 1, in a position prior to deployment. A means is shown in Fig. 2 compressing the resilient delivery members 106. The means is preferably a member, such as a sleeve 108, a portion of which is shown in cross-section in the view of Fig. 2. The sleeve 108 preferably extends over the length of the shaft 104. The sleeve 108 compresses the delivery members 106, maintaining them within the inner diameter of the sleeve 108 while the catheter 100 is stored, advanced to a desired site and, optionally, when the catheter 100 is withdrawn. When the distal end of the catheter 100 is properly positioned at the site of interest B, the delivery members 106 can be released by retracting the sleeve 108, allowing the delivery members 106 of the distal portion to flare outward beyond the outer diameter of the shaft 104 and sleeve 108, to preferably contact and bear against the lumen walls, as in Fig. 1. This ensures that the drug is delivered proximate the wall.

The means for compressing need only extend over the distal portion of the shaft 104 or over the delivery members 106 themselves. A ring, collar, short sleeve or thread can also be used to compress the members. Thread, tubes or rods, for example, can also be coupled to the means for compressing, to withdraw the means for compressing from the delivery members 106. An embodiment using thread to compress and release the delivery members is discussed in conjunction with Figs. 6-9, below.

1           Drugs or other agents are delivered through delivery  
lumens 110 extending longitudinally through the shaft 104  
and delivery members 106, as shown in Fig. 3, to ports 112  
preferably located at the distal ends of the delivery  
5           members 106. The ports 112 deliver the drug proximate the  
wall of the artery where the fluid flow is very slow. A  
guide wire 114 and a guide wire lumen 116 extending axially  
through the shaft 104 are also shown in this view.

10           Preferably, the drug is delivered upstream of the  
site with respect to the blood flow so that the slow blood  
flow proximate the wall atraumatically carries the drug over  
the site. In Fig. 1, the direction of blood flow is  
indicated by an arrow A and the site is indicated by B.

15           Fig. 4 is a cross-sectional view of the catheter of  
Fig. 1 along line 4-4. The guide wire lumen 116 and the  
eight drug delivery lumens 110, one for each delivery member  
106, are shown. The same drug or agent can be delivered  
through all eight lumens and members, or different drugs or  
agents can be delivered through some or all of the lumens  
20           and members. While the term "drug" is generally used  
hereafter, it is understood that other agents can be  
delivered as well.

25           The number of delivery members 106 can vary. The  
preferred number can depend on the diameter of the vessel  
where the drug is to be delivered. For example, eight  
delivery members 106 are preferably provided in this  
embodiment, which will enable an even distribution of the  
delivered drug around the circumference of the arterial wall  
in an artery with a diameter of between about 2.5-5 mm.  
30           Additional delivery members 106 could be preferred for  
larger vessels, while fewer can be used in smaller vessels.  
The delivery members 106 are preferably integral portions of  
the catheter shaft 104, and are of the same polymeric  
material as the shaft 104.

35           As mentioned above, the delivery members 106  
preferably bear against the wall of the lumen when fully  
deployed to ensure drug delivery proximate the walls of the  
artery. The force with which the members 106 bear against  
the wall also prevents the members 106 from being displaced

1 from the walls of the artery, or other such lumen, by blood or fluid flow. In coronary arteries, the pumping of the heart could also displace the members. The bearing force is insufficient to damage the walls of the vessel.

5 To provide such a stabilizing, bearing force, the delivery members 106, when fully extended, preferably have an outermost diameter D, measured across a circumference defined by the outer tips of the members, as shown in Fig. 3, slightly greater than the diameter of the vessel. The  
10 delivery members 106 preferably extend from the shaft at an angle of between about 25-50° when fully deployed. The wall of the vessel or lumen preferably compresses the delivery members 10-50% from their fully flared positions. The lesser of 10% or 0.4 mm compression of the diameter is most  
15 preferred. Preferably, the ratio between the diameter D when fully flared and the horizontal distance H from the shaft 104 to a projection of the tip of the member to the longitudinal axis, is between about 2:1 to 1:1, to achieve sufficient bearing force against the lumen wall.

20 For example, the diameters of the arteries can vary between about 2.5-8.0 mm. If the catheter is intended for use in an artery with a diameter of about 3.0 mm, the delivery members are preferably configured to have an outer diameter D of about 3.3 mm when fully extended. If the  
25 members 106 flare from the shaft 104 at an angle of about 45°, the length L of the members 106 would be about 2.3 mm. For use in a larger artery, with an inner diameter of about 8 mm, for example, the diameter D between opposing members can be about 8.4 mm. If the members 106 flare from the  
30 shaft 104 at an angle of about 45°, the length of each member 106 is about 6 mm.

35 The inner diameters of the delivery lumens 110 and their ports 112 are preferably between about 0.005-0.010 inches. If greater drug delivery is desired, larger delivery lumens 110 can be provided.

The diameters of the shaft 104 and sleeve 108 may vary dependent upon the diameter of the intended site. For example, in regions of arteries having diameters of between about 2.5-5 mm, the outer diameter of the sleeve 108 can be

1 about 0.065 inches or less. The inner diameter of the  
sleeve 108 is preferably about 0.055 inches. The outer  
diameter of the shaft 104 can be about 0.045 inches.  
Clearance 117 is preferably provided between the sleeve 108  
5 and the shaft 104 to ease the movement of one with respect  
to the other, as shown in Figs. 2-4. A larger diameter  
catheter may be desired for a site with a larger diameter  
while a smaller diameter catheter may be used for a narrower  
site. The diameter of the guide wire lumen 116 can be about  
10 0.022 inches, for example.

When flared, the drug delivery members 106 are  
separated by sufficient space to allow for significant  
perfusion of blood between the members. This increases the  
possible length of surgical procedures, without requiring  
15 perfusion means which can increase the complexity of the use  
and manufacture of the catheter.

Returning to Fig. 1, the sleeve 108 preferably  
includes a radiopaque band 118 of gold or tantalum, for  
example, at its distal end, to assist in tracking the  
20 progress of the catheter on a fluoroscope during a  
procedure. The shaft 104 also preferably includes a  
radiopaque band 120, preferably just proximal to the point  
where the delivery members 106 separate from the shaft 104.  
The bands 118, 120 are preferably positioned such that when  
25 the radiopaque band 118 of the sleeve 108 is essentially  
aligned with the radiopaque band 120 of the shaft 104, the  
sleeve 108 has been sufficiently retracted to release the  
delivery members 106, as shown in Fig. 3. The sleeve 108  
may be further retracted from the distal end of the shaft  
30 104 during use, as well.

The sleeve 108 and shaft 104 preferably comprise  
materials which will easily slide with respect to each  
other. The shaft 104 is also preferably a thermoplastic  
elastomer with shape memory capability with proper  
35 processing, as described below. The shaft 104 can be a  
thermoplastic elastomer resin such as a polyether block  
amide (PEBA). PEBAX®, available from Atochem Inc., New  
Jersey, is one such material. A hardness of between about  
25-50 Shore D is preferred for the shaft 104, with a

1 hardness of 40 most preferred. The characteristics of an  
appropriate material, PEBAX® grade 4033 SA 00, for example,  
appear below:

5	Hardness	Shore D	40
		Shore A	90
10	Melt Flow Rate		3-7
	ASTM D1238 Q		
	2 mm orifice		
15	Water Absorption		1.2%
	24 hours		
	ASTM D 570		
20	Equilibrium		0.5%
	20°C/65% RH		
	Elongation		485%
25	ASTM D638		
	At Break		
	Tensile Strength		36 MPa
30	ASTM D638		5220 psi
	At Break		
	Flexural Modulus		75 MPa
35	ASTM D790		10,900 psi
	Maximum Flexure		27 mm
	ASTM D790		1.06 inches
30	Stress		4.3 MPa
	ASTM D790		624 psi
	Resilience		62.5%
35	BS 903 Part 08		
	Method A		
	Melting Point (Optical)		168°C
	ASTM D2117		334°F

1

Melting Range DSC	119-170°C
ASTM D3418	246-338°F

5

Vicat Softening Point	132°C
ASTM D1525	270°C

10

Hytrel®, a polyester elastomer available from Du Pont, Wilmington, Delaware, and all the known grades of polyethylene, such as linear low density polyethylene (LLDPE), low density polyethylene (LDPE), high density polyethylene (HDPE) and ultra high density polyethylene (UHDPE), and other thrombogenic materials which are appropriate for catheter shafts and can exhibit shape memory characteristics, can be used, as well.

15

An appropriate material for the sleeve 108 is Marlex HHM 4903 HDPE, for example, available from Phillips 66, Pasadena, Texas. Characteristics of Marlex HHM 4903, appear below:

20

Melt Index	0.30 g/10 min
Condition 190/2.16	
D 1238	

25

Tensile Yield Strength	3600 psi
2 in. (50 mm) per min.	
D 638	25 MPa
Type IV	

30

Ultimate Elongation	>600%
2 in. (50 mm) per min.	
D 638	
Type IV	

35

Flexural Modulus	170 psi
D 790	1171 MPa

Another appropriate material for the sleeve 108 is Hytrel® 5556. It may be desirable when using Hytrel® 5556

1 to provide a distal portion of the shaft of a softer  
material, such as Hytrel® 4056, for improved flexibility and  
to prevent tissue damage.

5 Characteristics of Hytrel® 5556 and 4056 appear  
below:

	Hardness	55 Shore D	40 Shore D
	D 2240		
	Melting Point	201°C	145°C
10	Peak of Endotherm		
	Melt Complete	220°C	170°C
	D 3418		
	Tensile Strength	44 MPa	30 MPa
15	D 638		
	Ultimate Elongation	560%	560%
	D638		
20	Flexural Modulus	207 MPa	48 MPa
	D 790		
	Resilience	53%	62%
	Bashore		
25	Compression Set	4%	27%
	22 hours at 70°C		
	Constant Load (9.3 MPa)		
	D395A		
30	Vicat Softening Point	180°C	112°C
	D1525		

35 Other non-thrombogenic materials can be used as  
well. For example, the sleeve 108 can comprise PEBAX®, with  
a hardness of 55, for example, polytetrafluoroethylene  
(PTFE), polyethylene, fluorinated ethylene propylene (FEP),  
and all the known grades of polyethylene such as LLDPE,  
LDPE, HDPE and UHDPE.



1           To further ease movement of the sleeve 108 with  
respect to the shaft 104, a lubricous coating of silicone,  
for example, is provided over the shaft 104. To ease  
transport through the guide catheter and in the vessel, the  
5   lubricous coating is preferably provided over the sleeve  
108, as well.

          If the preferred materials for the sleeve 108 and  
shaft 104 are not rigid enough to be easily advanced along  
the guide wire 114 through a guide catheter, a reinforcing  
10   sleeve 122 of stainless steel, titanium, or titanium nickel,  
for example, may be provided within the guide wire lumen  
116, as shown in Figs. 3-5. The reinforcing sleeve 122  
preferably extends from the proximal end of the catheter  
100, more than half the length of the catheter 100, up to  
15   about 12 inches or about 30 mm from the distal end of the  
shaft 104. Where the guide wire lumen 116 is about 0.022  
inches, the reinforcing sleeve 122 can have an outer  
diameter of about 0.020 inches and an inner diameter of  
about 0.016 inches, for example.

20           Other means of reinforcing the catheter can be used  
as well. For example, the sleeve 108 can be reinforced  
instead of the shaft 104. A rigid wire or stylet can also  
be embedded within the sleeve 108 or shaft 104. Irradiation  
of the sleeve or shaft with an electron beam to increase the  
25   cross-linking and hence the stiffness of the polymeric  
material, can also be used, as is known in the art. A  
harder material can also be used for the sleeve 108 or shaft  
104 than those preferred above, in which case the distal  
portion of the sleeve or shaft may need to be "necked down"  
30   to decrease its outer diameter, increasing its flexibility.

          The catheter 100 of the present invention can be  
used to deliver antiproliferatives, anticoagulants, or  
antiplatelet agents, such as heparin, dexamethasone, and  
Integralin, to the site of a PTCA, PTA or stent procedure to  
35   prevent restenosis, for example. The drug can be delivered  
before or after the dilatation procedure. It can also be  
used to deliver lytic agents, such a urokinase,  
streptokinase or rTPA to the site of a thrombus in an artery  
or vein. A preferred configuration for use in a vein is

1 shown in Figs. 16-19, and described further below. Other  
drugs and agents known or to be developed, could be  
delivered, as well.

5 Fig. 5 is a cross-sectional view of the proximal  
portion of the catheter 100, including a manifold 124 for  
providing a drug or other agent into the delivery lumens  
110. The drug is supplied from a drug infusion unit 126 or  
a syringe (not shown) through a first port 128. The guide  
10 wire 114 can extend through a second port 130. A ring 132  
at the proximal end of the catheter 100 is attached to the  
sleeve 108 to advance or retract the sleeve. The sleeve 108  
is retracted by withdrawing the ring 132 a sufficient  
distance so that the distal portion of the sleeve 108 is no  
longer compressing or restraining the delivery members 106.  
15 Advancing the ring 132 advances the sleeve 108 back over the  
delivery members 106.

A seal, such as an O-ring 133 of latex or silicone,  
for example, is provided between the ring and proximal  
portion of the catheter shaft 104 to prevent leakage. A  
20 port 135 can be provided through the ring 132 to enable  
venting of air. Saline may also be delivered through the  
port 135 to maintain the clearance 117 open. The port 135  
could also be used to delivery a drug or other agent, such  
as heparin, into the vessel. The manifold 124 can be easily  
25 modified to deliver different drugs or other agents through  
different ports, as well.

In use, the catheter 100 of the invention can be  
advanced to the site of interest B over the guide wire 114  
through a guide catheter (not shown). The delivery members  
30 106 are preferably positioned such that drug will be  
delivered upstream of the site of interest with respect to  
the blood flow. For example, if the catheter 100 is  
advanced along the direction of blood flow, the drug  
delivery would preferably be proximal to the site B, as in  
35 Fig. 1. If the catheter 100 is advanced in a direction  
opposing the blood flow, the drug delivery would preferably  
be distal to the site, as in Fig. 16.

When the catheter 100 is properly positioned, the  
sleeve 108 is retracted by withdrawing the ring 132 a

1 sufficient distance. Preferably, this can be observed by  
the alignment of the radiopaque bands 118, 120 on the shaft  
108 and sleeve 104, as shown in Fig. 3. The delivery  
members 106 would then rotate through an acute angle, to the  
5 position of Fig. 1. The drug or other agent is then  
delivered proximate the vessel wall. The slow blood flow  
proximate the vessel wall will atraumatically carry the  
delivered drug over the site B. Perfusion of blood is not  
impeded, as blood or other fluids will flow between the  
10 delivery members. If desired or necessary, the sleeve 108  
can be retracted further than shown in Figs. 1 or 3.

When sufficient drug has been delivered, the sleeve  
108 can be advanced back over the distal portion of the  
shaft 104 or the shaft 104 can be withdrawn into the sleeve  
15 108. The catheter 100 can then be removed through the guide  
catheter. It is also possible to remove this embodiment of  
the invention through the guide catheter while it is in the  
deployed position. In addition to delivering drugs through  
the members, the guide wire 114 can be removed and drugs can  
20 be delivered through the guide wire lumen 116. This could  
be particularly useful in the treatment of thrombosis, where  
the drug can be directed toward the center of the thrombus,  
as well as its periphery along the wall of the vessel. In  
addition, while the drug is preferably delivered proximate  
25 the wall of the vessel or lumen, drug can be delivered at  
various locations across the cross-section of the vessel by  
varying the degree to which the sleeve is retracted. Drugs  
can also be delivered through port 135, of Fig. 5, through  
the clearance 117 between the sleeve 108 and shaft 104.

30 Figs. 6-9 show a variation in the embodiment of  
Figs. 1-4, wherein instead of a sleeve 108, a thread 140  
restrains and compresses the delivery members 106. The  
thread 140 can be tied around the periphery of the delivery  
members 106, in a releasable knot 142, such as a horse  
35 thief's knot, shown in Fig. 9E. Formation of a horse  
thief's knot is shown in Figs. 9A-9D. First, a loop 144 is  
formed at one end of the thread 140, beneath the delivery  
members 106. For illustrative purposes, the delivery  
members are not shown in these views. The loop 144 has a

1 short end 146 and a long end 148. A portion 150 of the  
short end 146 is carried over the members and beneath the  
loop 144 as shown in Fig. 9B, to form a second loop 152, as  
shown in Fig. 9C. The long end 148 is then carried under  
5 the short end 146, over the first loop 144 and through the  
second loop 152. The short end 146 is pulled to tighten the  
knot. Pulling the long end 148 releases the knot, allowing  
the delivery members 106 to flare to their deployed  
position.

10 The long end 148 of the thread 140 can extend over  
the exterior of the shaft 104 as shown in Fig. 6, through a  
lumen within the shaft 104, such as the guide wire lumen  
116, as shown in Fig. 7 or through a delivery lumen 110 as  
shown in Fig. 8. The guide wire lumen 116 can be divided  
15 into two lumens, one for the guide wire 144 and one for the  
thread 140. The thread 140 can be nylon, for example. The  
thread can have a diameter between about 0.005-0.008 inches,  
for example. The use of a thread 140 instead of a sleeve  
decreases the outer diameter of the catheter and may  
20 therefore be particularly suited for use in small vessels,  
such as cerebral arteries which can have diameters of about  
1.0-2.5 mm, for example. The proximal portion of the  
catheter as shown in Fig. 5 can be suitably modified for use  
with this embodiment. For example, no ring 132 is required  
25 to retract a sleeve.

Fig. 10 shows a catheter 200 in accordance with a  
third embodiment of the invention wherein the delivery  
members 202 comprise a first, tapered portion 204 and a  
second, longitudinal portion 206. A series of ports 208 can  
30 be provided along the tapered and longitudinal portions for  
delivering drug proximal to the site of interest. A single  
port can be provided at the distal end of the member, as in  
the embodiment of Fig. 2, as well. The drug can also be  
delivered directly onto the site of interest. The ports 208  
35 can have a diameter of about 0.005-0.010 inches. The  
remainder of the catheter 200 is the same as above.

Fig. 11 is a partial cross-sectional view of the  
catheter 200 wherein the delivery members 202 are within and  
compressed by a sleeve 210. The sleeve 210 is shown in

1 partial cross-section in this view. Delivery lumens 212 and  
guide wire lumen 214 are shown as well. The delivery  
members 202 can be compressed by a thread, as in Figs. 7-9,  
or other compressing means, as well. The proximal portion  
5 of the catheter 200 can be the same as that shown in Fig. 5.

To manufacture the catheters of the embodiments of  
Figs. 1-9, in accordance with the present invention, the  
shaft 104 can be extruded in a multi-lumen extrusion  
process, as is known in the art. One or both ends of the  
10 extrusion can have a tapered portion leading to a wider  
longitudinal region, to ease subsequent operations on the  
shaft. Such wider regions can be formed by a bump extrusion  
process, also known in the art.

The delivery members 106 are formed by cutting the  
15 distal end of the shaft 104 between each of the delivery  
lumens 110 a desired length depending on the desired length  
for the members. A blade or other thin cutting surface is  
preferred. The shaft can be cut by hand or by a machine.  
The machine can include a mounting for securing the shaft  
20 and a series of cutting blades disposed radially to  
simultaneously cut the distal portion of the shaft along its  
longitudinal axis. The number of blades corresponds to the  
number of delivery members desired. The thickness of the  
blades is preferably less than 0.010 inches. A thickness of  
25 about 0.005 inches or less is most preferred. If a bump  
extrusion is used to form the distal end, the distal end is  
cut through the taper to shorten that end, before cutting  
the shaft. The shaft can be cut with a laser, as well.

As mentioned above, the length of the delivery  
30 members 106 can vary depending on the application. The  
length of all the delivery members is preferably the same,  
which enhances the ability of the members to deploy after  
retraction of the sleeve.

To form the flare in the embodiment of Figs. 1-6, a  
35 tool, such as the tool 300 shown in Fig. 12, is inserted  
within the guide wire lumen 114 of the extruded shaft 104,  
after the distal portion is cut, as shown in Fig. 12. The  
tool 300 comprises a rod shaped guiding mandrel or wire 302  
depending from a conical surface 304. As the distal ends of

1 the delivery members 106 engage the conical surface, they  
are forced outward, as shown in the cross-sectional view of  
Fig. 13. The tool 300 is advanced to the uncut portion of  
the shaft. When the tool 300 is suitably positioned, the  
5 shaft 104 and tool 300 are placed in an oven at about 225°-  
250°F for about 5-30 minutes, to heat set the delivery  
members 106. In this embodiment, the angle of the flare is  
preferably between about 25°-50°. If the bump extrusion  
process is used for the distal end, the delivery members 106  
10 will already be partially tapered. The extent of additional  
flaring after cutting may not then be as great. The tool  
300 can be made of brass, stainless steel or PTFE, for  
example.

After heat setting, the reinforcing sleeve 122 is  
15 inserted into the shaft 104. Radiopaque bands 118, 120 are  
preferably applied to the shaft 104 and sleeve 108. A  
lubricous coating is applied to the shaft 104 and the sleeve  
108 is placed over the shaft 104 or the thread 140 is tied  
to the delivery members 106.

20 In manufacturing the embodiment of Figs. 10-11,  
wherein the delivery members 202 include the second,  
longitudinal portion 206, the distal end of the shaft is  
preferably not bump extruded. The first, flared portion of  
the delivery members 106 can be formed with the same tool as  
25 used in the first embodiment. The tool 300 is advanced  
until the members 202 extend beyond the conical portion of  
the tool the desired length of the first longitudinal  
portion 206, as shown in Fig. 14. A tube or collar 400 with  
a diameter slightly greater than the diameter of the tool  
30 300, is then passed over the proximal end of the shaft, and  
over the first tool 300, ensuring that the delivery members  
202 bear against the wall of the first tool 300, as in the  
cross-sectional view of Fig. 18. The shaft is then heated,  
as above. The ports can be formed by a punch, drill or  
35 laser, as is known in the art.

Figs. 16-19 show another embodiment of the present  
invention, particularly suited for use in a vein, such as  
the inferior vena cava, or in cerebral arteries. The  
catheter 500 is the same as the catheter 100 in Figs. 1-6,

1 except that the delivery members 502 extend rearwardly from  
the distal end of the shaft 504, as shown in the side view  
of Fig. 16. The delivery ports 506 are preferably located  
at the end of the delivery members 502. A plurality of  
5 ports can be provided along the inside surfaces of the  
delivery members 502, as well. This configuration is  
preferred for delivering drugs or other agents in a vein  
because in such applications, the catheter is typically  
inserted into the jugular or femoral vein, in a direction  
10 opposite the blood flow, indicated by arrow C in Fig. 16.  
This configuration delivers the drug or other agent  
proximate the vessel wall, in the direction of the blood  
flow. The blood then slowly carries the delivered drug  
atraumatically across the intended site, indicated by E.  
15 Delivery in a direction opposite the blood flow could cause  
eddy currents, preventing laminar flow along the vessel  
wall.

Fig. 17 is a cross-sectional view of the catheter  
500 of Fig. 16, showing the delivery lumens 508 and guide  
20 wire lumen 510. Fig. 18 is a cross-sectional view of the  
catheter 500 through line 18-18 in Fig. 16. Fig. 19 is a  
cross-sectional view of the catheter 500 wherein the  
delivery members 502 are received within and compressed by  
the sleeve 512. The proximal portion of the catheter 500  
25 can be the same as that shown in Fig. 5.

As above, the dimensions of the catheter 500 depend  
on the intended site. For example, the cerebral arteries  
have a diameter of about 1.0-2.5 mm. Veins, on the other  
hand, can have diameters of about 6-10 mm. The members 502  
30 preferably have a diameter when fully flared slightly  
greater than the diameter of the vessel itself, to ensure  
that they bear against the walls of the vessel. The  
delivery members 502 preferably rotate through an angle  
between 115°-140° to reach the position of Fig. 16.

35 To treat thrombosis, for example, with this  
embodiment of the invention, the catheter 500 can be  
inserted through a guide catheter and over a guide wire,  
through the thrombus. When the distal portion of the  
catheter is positioned sufficiently beyond the distal

1 portion of the thrombus, the sleeve 512 can be retracted,  
releasing the delivery members 502 which rotate through an  
obtuse angle to the position of Fig. 18. The catheter 500  
may need to be advanced slightly to enable the delivery  
5 members 502, whose diameter is slightly larger than that of  
the vessel, to fully rotate. A lytic agent, such as  
urokinase, streptokinase or rTPA, is then delivered.  
Integralin may be delivered, as well. Any other drug or  
agent known or to be developed which is efficacious in  
10 dissolving a thrombus, may also be used. Blood flow and the  
pressure of delivery carry the delivered drug towards the  
thrombus. The drug is administered until the thrombus is  
dissolved. When the thrombus is dissolved, the sleeve can  
be advanced over the distal portion of the catheter prior to  
15 its withdrawal.

This configuration can also be used as a filter to  
catch and remove a thrombus or plaque. The members 502 can  
be solid, or can include lumens and a series of ports along  
its surfaces for drug delivery, to dissolve material caught  
20 by the members 502. The catheter 500 can be inserted  
through and beyond a thrombus, and deployed. The distal  
portion of the catheter can then be withdrawn into the guide  
catheter, which would be positioned proximal to the  
thrombus, together with the thrombus.

25 Alternatively, the catheter can be deployed in a  
location within a vein or artery to catch thrombolytic  
material which may pass. A lytic agent, such as those  
discussed above, can be delivered prior to and during  
removal of the thrombolytic material by the members. A  
30 plurality of ports to allow the delivery of drug along the  
inside surface of the delivery member can be provided to  
enable the delivery of a lytic agent directly onto  
thrombolytic material caught by the members 502. This  
embodiment could be particularly useful in cerebral  
35 arteries.

It may also be advantageous to use the embodiment of  
Figs. 1-4 and 16-19 together to apply lytic agent to the  
proximal and distal sides of the thrombus. First, the  
catheter 100 can be deployed proximal to the thrombus. Then



1 the catheter 500 can be advanced through and distal to the  
thrombus over the same guide wire 114 as the catheter 100,  
through the guide wire lumen 116 of the catheter 100.  
Alternatively, the catheter 500 could be deployed first  
5 distal to the thrombus and the embodiment of catheter 100  
can then be advanced over it. Lytic agent can then be  
simultaneously or sequentially supplied through both  
catheters.

Figs. 20-23 illustrate the formation of the  
10 embodiment of Figs. 16-19. After cutting the distal portion  
of the shaft 504, the tool 300 of Fig. 12 is used to flare  
the members 502. When the members extend past the side  
walls of the tool 300, as in Fig. 20, a tube or collar 600  
is advanced over the distal end of the tool, engaging and  
15 forcing the portions of the delivery members backward, as  
shown in Fig. 21. The first tool is then removed and a  
second tool 602, shown in cross-section in Fig. 22, is  
attached to the collar 600. A wire or mandrel 603 depends  
from the tool 602 and is inserted into the shaft as shown.  
20 The second tool 602 is configured to match the desired  
position of the members 502 when fully deployed. The shaft  
is advanced in the direction of the arrow from the collar  
600 into the second tool 602, over the wire 603. When the  
shaft 104 is completely within the second tool 602, the  
25 delivery members 502 conform to the curvature of the  
surfaces 604 of the second tool 602, as shown in Fig. 23.  
The collar 600 is then removed.

The catheter shaft with the tool 602 in place is  
heated at about 225-250°F for 5-30 minutes. The catheter  
30 shaft is then prepared as above.

Figs. 24-26 illustrate a catheter 700 with an  
expandable distal portion which can be used for drug  
delivery, as a thrombolytic filter with clot lysing  
capability, or merely as a thrombolytic filter, in  
35 accordance with another embodiment of the invention. Fig.  
24 is a side view of the catheter 700 in its deployed  
position in the vena cava, for example. The catheter 700  
comprises a shaft 702 with an expandable distal portion and  
a means for compressing the expandable portion, preferably a

1 sleeve 704. Other means for compressing, as described  
above, may be used as well. The distal portion preferably  
comprises a plurality of longitudinal ribs 706 having  
proximal and distal ends depending from the shaft 702.  
5 Other configurations, such as overlapping ribs, can also be  
used. A central portion of the ribs 706 flare radially  
beyond the outer diameter of the catheter shaft, between the  
proximal and distal ends of the ribs 706. A portion of the  
ribs 706 preferably bear against the wall of the vena cava,  
10 as shown in Fig. 24. As above, the diameter D of the ribs  
706 in their fully flared position, measured across the  
center of the outer periphery of a region defined by the  
ribs, as shown in Fig. 25, is preferably greater than the  
diameter of the site, ensuring that the ribs bear against  
15 the wall, as shown in Fig. 24.

The longitudinal ribs 706 can be of any desired  
length, and preferably vary between 6-10 mm. The greatest  
diameter D of the longitudinal ribs 706 when fully flared is  
preferably 1.5-2 times their length L, as shown in Fig. 25.  
20 Eight lumens are provided in this embodiment, but more or  
less can be used, depending on the size of the lumen or  
vessel at the site of interest.

At least one and preferably a series of ports 708  
are provided in each rib 706. Delivery lumens 710 provide  
25 drugs or other agents to the ports 708, as shown in Fig. 25.  
A guide wire lumen 712 is provided, as well. If only to be  
used for drug delivery to the walls of the vessel, such as  
to prevent restenosis, the ports 708 preferably extend  
outward. If the catheter is to be used as a thrombolytic  
30 filter, additional ports are preferably provided at the  
sides of the ribs, for drug delivery between the ribs, and  
along the underside of the ribs, for drug delivery to the  
region within the ribs. The ports 708 are preferably about  
0.005 inches, and can be formed by a punch, drill or laser.  
35 Slits, which can be made by a blade or laser, can be used  
for drug delivery, as well. A lytic agent, such as those  
discussed above, or any other useful drug or agent known or  
to be discovered, can be delivered to dissolve thrombolytic  
material caught by the filter. The proximal portion of the

1 catheter 700 can be the same as that shown in Fig. 5. The remainder of catheter 700 can be the same as the embodiments above.

5 Fig. 26 is a partial sectional view of the catheter of Fig. 24, wherein the distal portion of the shaft is completely within the sleeve 704. The sleeve compresses the distal portion of the shaft so that its diameter is less than that of the sleeve 704. The catheter 700 is stored, advanced to the desired site, and preferably withdrawn in  
10 this configuration.

The catheter 700 can be advanced to its desired site through a guide catheter, for example, in the configuration of Fig. 26. When the site is reached, the sleeve 704 is retracted, releasing the distal portion of the catheter  
15 shaft, allowing the longitudinal ribs 706 to flare outward as shown in Fig. 24. Blood or other fluids can flow through the region defined by the ribs 706. Thrombolytic material greater than the distance between the ribs will be caught by the ribs. When the filter is to be removed, the sleeve 704  
20 is advanced or the shaft 702 is retracted such that the distal portion of the shaft is within the sleeve.

If only filtration is desired, the ribs can be solid. No delivery lumens would then be required, either.

The catheter 700 of this embodiment can be  
25 manufactured of the same materials as described above. The catheter shaft 702 is first extruded, including the delivery lumens 710 if necessary. A wire is then inserted through the distal portion of the guide wire lumen 712. A series of radial longitudinal cuts which do not extend to the distal  
30 end of the shaft, are then made with a cutting blade or razor through the shaft, to the guide wire lumen 712, to define the longitudinal ribs 706. The wire is removed and an oblong shaped tool 714, made of brass, stainless steel or PTFE, for example, is then inserted between the ribs. A  
35 perspective view of the tool 714 is shown in Fig. 27. A cross-sectional view of the tool 712 and two ribs 706 is shown in Fig. 28. The tool preferably includes an opening 716 along its longitudinal axis for receiving a wire 718 inserted through the distal end of the shaft 702. The wire

1     718 helps to maintain the tool 714 centered between the ribs  
706. The shaft 702 and tool 714 are then heated in an oven,  
as above. Subsequent processing is the same as above, as  
well.

5             The above embodiments are examples of  
implementations of the present invention, which is defined  
in the following claims.

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1           We claim:

1.   A catheter comprising:

5           a delivery portion comprising a shaft, at least one resilient delivery member at the distal portion of the shaft, and at least one delivery lumen extending longitudinally through the shaft and delivery member, the delivery member including at least one delivery port in fluid communication with the delivery lumen, wherein the delivery member is capable of extending from the shaft at an angle with respect to a longitudinal axis through the catheter shaft;

10           a means for compressing the delivery member, wherein when the means for compressing is removed from the delivery members, the delivery members flare to the angle with respect to the catheter shaft.

15           2.   The catheter of claim 1, wherein the angle is acute.

          3.   The catheter of claim 1, wherein the angle is obtuse.

20           4.   The catheter of claim 2, further comprising a guide wire lumen.

          5.   The catheter of claim 1, wherein the port is located at a distal end of the delivery member.

25           6.   The catheter of claim 1, wherein the delivery member is adapted to bear against the delivery site when the delivery member flares to the angle.

          7.   The catheter of claim 1, wherein the delivery member is integral with the shaft.

30           8.   The catheter of claim 1 wherein the means for compressing comprises a sleeve extending the length of the shaft, wherein the shaft is received within the sleeve.

          9.   The catheter of claim 1, wherein the means for compressing comprises a thread tied about the delivery members, and extending the length of the catheter shaft.

35           10.   The catheter of claim 9, wherein the thread extends through a lumen extending longitudinally through the shaft.

1           11. The catheter of claim 1, wherein the different  
drugs or other agents are delivered through different  
delivery lumens.

5           12. A catheter comprising a shaft having distal  
and proximal portions, and a sleeve, wherein the shaft is  
received within the sleeve and the shaft and sleeve are  
adapted to be moved with respect to each other;

10           the shaft comprising a plurality of resilient  
delivery members extending from the distal portion of the  
catheter shaft at an acute angle with respect to a  
longitudinal axis of the catheter shaft when the sleeve is  
retracted from the distal portion, the delivery members  
being compressed by the sleeve when the distal portion of  
the shaft is received within the sleeve, a plurality of  
15           delivery lumens corresponding to the number of delivery  
members, the delivery lumens extending through the catheter  
shaft and delivery members; and

            at least one delivery port in each delivery  
member.

20           13. The catheter of claim 12, wherein the catheter  
shaft further comprises a guide wire lumen.

            14. The catheter of claim 12, wherein the delivery  
members are compressed to a diameter less than the inner  
diameter of the sleeve.

25           15. The catheter of claim 12, wherein the delivery  
members are essentially aligned with a longitudinal axis of  
the shaft when compressed.

            16. The catheter of claim 12, wherein the delivery  
members are of polymeric material.

30           17. The catheter of claim 12, wherein different  
drugs or other agents are delivered through different  
delivery lumens.

35           18. The catheter of claim 12, wherein the delivery  
lumens are adapted to bear against a delivery site when the  
sleeve is retracted.

            19. A catheter comprising a shaft having distal and  
proximal portions, and a sleeve, wherein the shaft is  
received within the sleeve and the sleeve and shaft can move  
with respect to each other;

1           the shaft comprising a plurality of resilient  
delivery members flaring from the distal portion of the  
shaft at an acute angle with respect to a longitudinal axis  
of the catheter shaft when the sleeve is retracted from the  
5       distal portion,

          wherein the delivery members comprise a first,  
tapered portion having a distal end and extending at the  
angle with respect to the longitudinal axis of the catheter  
shaft, and a second, essentially longitudinal portion  
10       depending from the distal end of first portion;

          a plurality of delivery lumens corresponding to  
the number of delivery members, the delivery lumens  
extending through the shaft and delivery members; and

          at least one delivery port in each delivery  
15       member.

20.   The catheter of claim 19, wherein the delivery  
members are of polymeric material.

21.   The catheter of claim 19, wherein the delivery  
lumens are adapted to bear against a delivery site when the  
20       sleeve is retracted.

22.   The catheter of claim 19, wherein different  
drugs or agents are delivered through different delivery  
lumens.

23.   A catheter comprising a shaft having distal and  
25       proximal portions, and a sleeve, wherein the catheter shaft  
is received within the sleeve and the sleeve and shaft can  
move with respect to each other;

          the shaft comprising a plurality of resilient  
delivery members having a first portion with a distal end  
30       extending rearwardly from the distal portion of the shaft  
when the sleeve is retracted from the distal portion,

          the shaft further comprising a plurality of  
delivery lumens extending through the shaft and the delivery  
members.

24.   The catheter of claim 23, wherein the delivery  
35       members extend forward and essentially parallel with a  
longitudinal axis extending through the shaft when the  
delivery members are within the sleeve.

1           25. The catheter of claim 23, wherein a diameter of the delivery members is less than a diameter of the sleeve when the delivery members are compressed by the sleeve.

5           26. The catheter of claim 23, wherein the delivery members are of polymeric material.

          27. The catheter of claim 23, wherein the delivery lumens are adapted to bear against a delivery site when the sleeve is retracted.

10          28. The catheter of claim 23, wherein different drugs or agents are delivered through different delivery lumens.

          29. A catheter comprising a shaft having distal and proximal portions, and a plurality of delivery members extending from the distal portion of the catheter shaft;

15           a thread tied about the delivery members wherein the delivery members flare from the catheter shaft at an angle with respect to a longitudinal axis of the catheter shaft when the thread is removed from the delivery members;

20           a plurality of delivery lumens corresponding to the number of delivery members, the delivery lumens extending through the catheter shaft and delivery members; and

25           at least one delivery port in each delivery member.

          30. The catheter of 29, wherein the thread extends the length of the shaft.

          31. The catheter of claim 29, wherein the thread extends over the exterior of the shaft.

30          32. The catheter of claim 29, wherein the thread extends through a lumen extending longitudinally through the shaft.

35          33. The catheter of claim 29, wherein the diameter of the delivery members when tied by the thread is no greater than the diameter of the shaft.

          34. The catheter of claim 29, wherein different drugs or agents are delivered through different delivery lumens.



1           35. A catheter comprising compressed, self-expandable delivery members which can be released to deliver drugs or other agents.

5           36. A catheter comprising a shaft having distal and proximal portions, and a sleeve, wherein the catheter shaft is received within the sleeve and the sleeve and shaft can move with respect to each other;

10                 the shaft comprising a plurality of resilient, solid members having a first portion with a distal end extending rearwardly from the distal portion of the shaft when the sleeve is retracted from the distal portion.

              37. The catheter of claim 36, wherein different drugs or agents are delivered through different lumen.

15           38. A method of delivering drugs or other agents to a lumen comprising:

                  advancing a catheter having compressed delivery members;

                  releasing the delivery members;

20                 delivering drugs or other agents through the catheter and delivery members.

              39. The method of claim 38, wherein the delivery members are compressed by a sleeve, the releasing step further comprising retracting the sleeve.

25           40. The method of claim 38, wherein the delivery members are compressed by a thread, the releasing step further comprising releasing the thread.

              41. The method of claim 38, wherein the delivery members bear against the lumen when released.

30           42. The method of claim 38, wherein the members flare to an acute angle with respect to a longitudinal axis of the catheter.

              43. The method of claim 38, wherein the members flare to an obtuse angle with respect to a longitudinal axis of the catheter.

35           44. The method of claim 43, further comprising advancing the compressed delivery members through a thrombus prior to releasing the delivery members.

1           45. The method of claim 44, further comprising  
removing the thrombus by the delivery members, by retracting  
the catheter.

5           46. The method of claim 38, further comprising  
delivering the drug or agent upstream of the an intended  
site with respect to the direction of blood flow within the  
lumen, such that the blood flow carries the delivered drug  
or agent over the site.

10          47. The method of claim 38, further comprising  
delivering different drugs or other agents through the  
catheter.

15          48. A method of treating thrombosis comprising:  
            advancing a first catheter with compressed  
delivery members proximal to the thrombus;  
            advancing a second catheter with compressed  
delivery members through the thrombus;  
            releasing the delivery members of the first  
catheter;  
            releasing the delivery members of the second  
20 catheter;  
            delivering drugs or other agents through the  
first catheter; and  
            delivering drugs or other agents through the  
second catheter.

25          49. The method of claim 48, further comprising  
removing the thrombus with the second catheter.

50. The method of claim 48, wherein the delivery  
steps comprise delivering a lytic agent through the first  
and second catheters.

30          51. A method comprising:  
            advancing a distal portion of a catheter having  
compressed, expandable solid members through a thrombus;  
            releasing the members to extend rearwardly from  
a distal end of the catheter; and  
35          removing the thrombus by retracting the  
catheter.

52. The method of claim 51, wherein the thrombus is  
removed by retracting the catheter into a guide catheter.

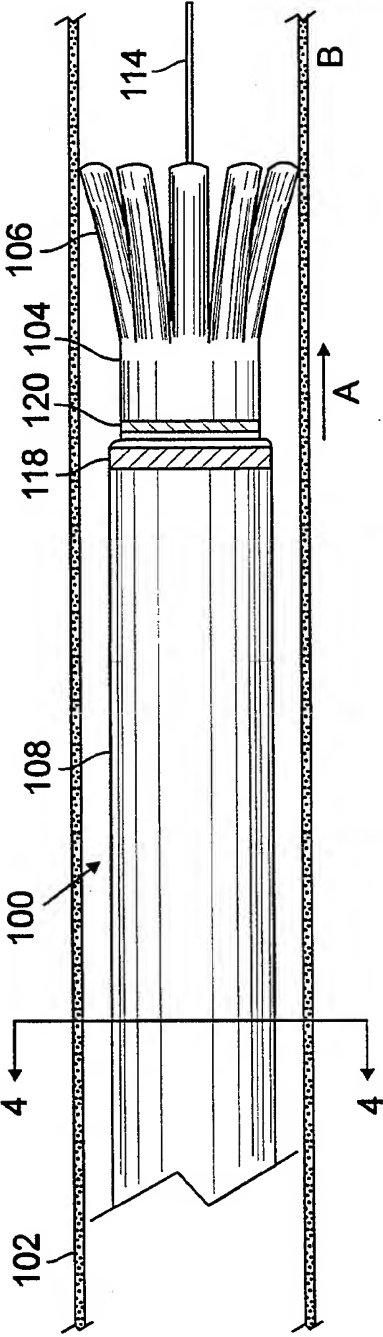


FIG. 1

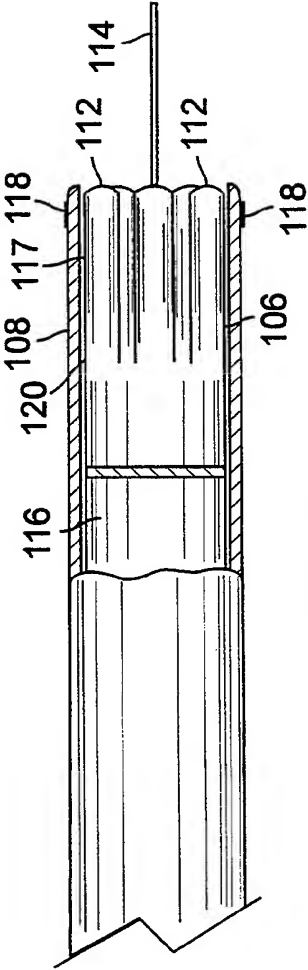
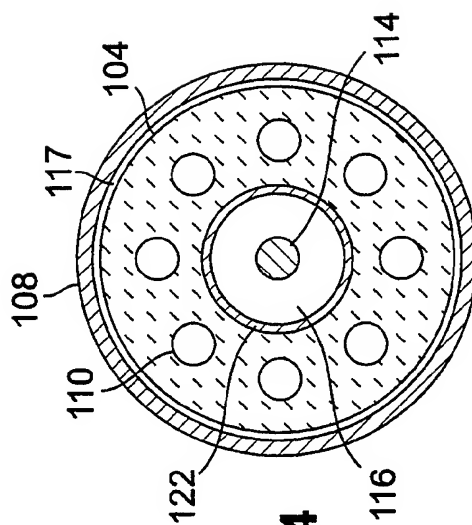
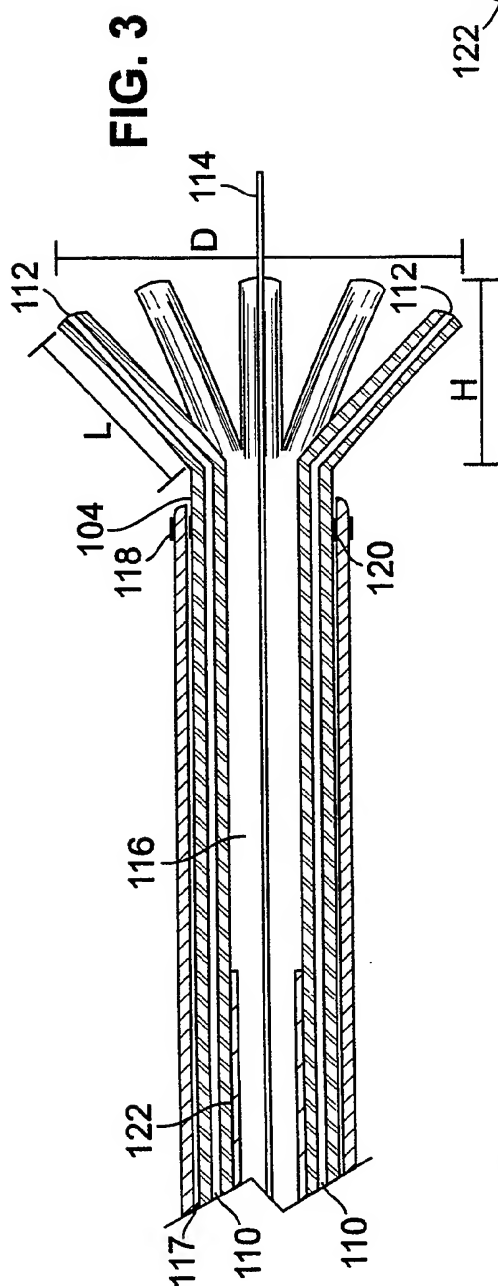


FIG. 2

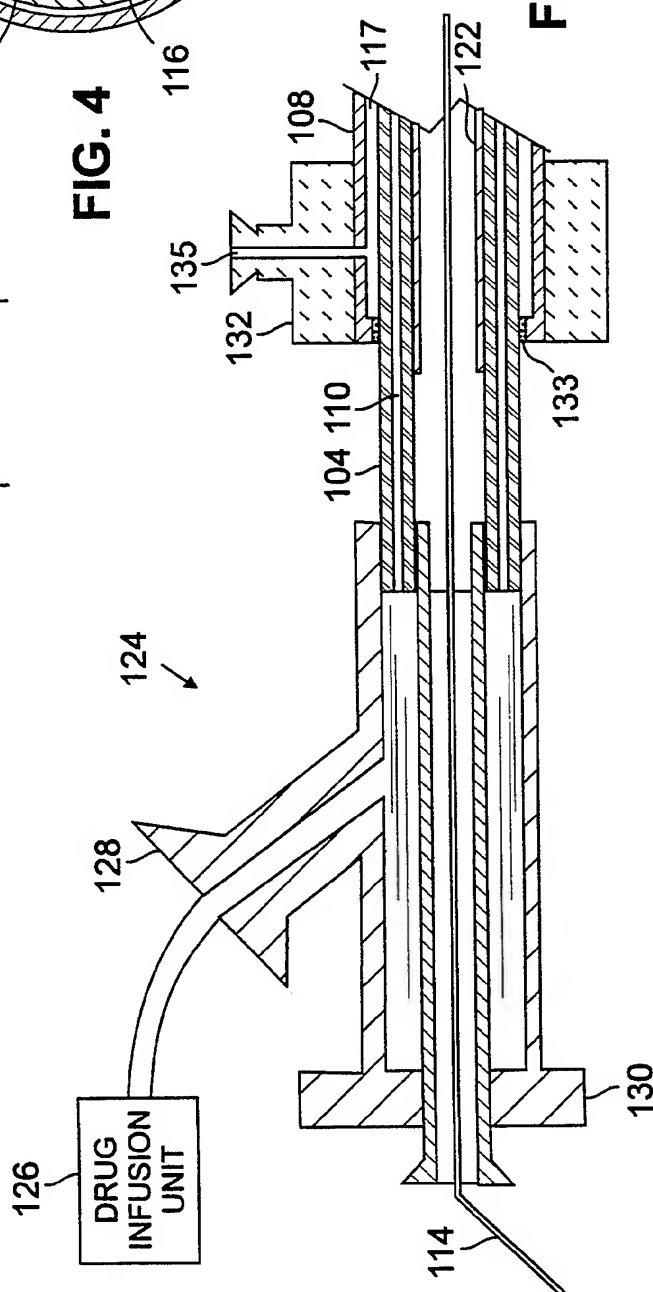
**2/12**



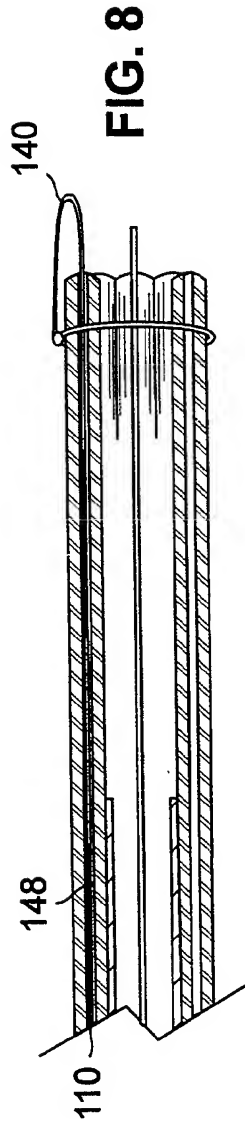
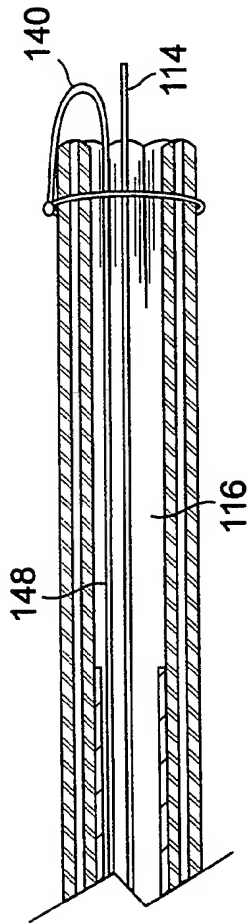
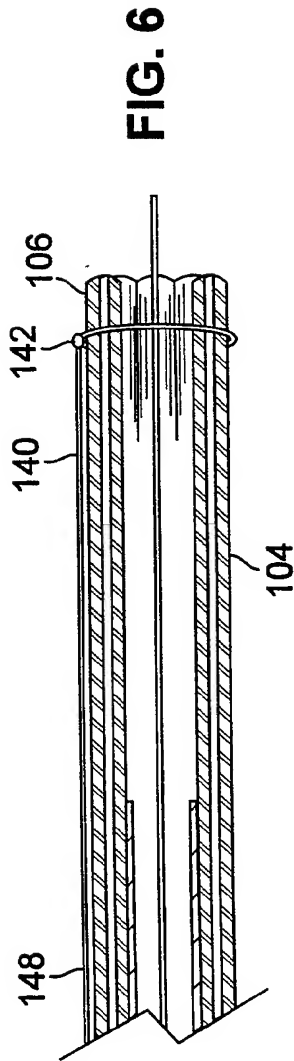
**FIG. 4**



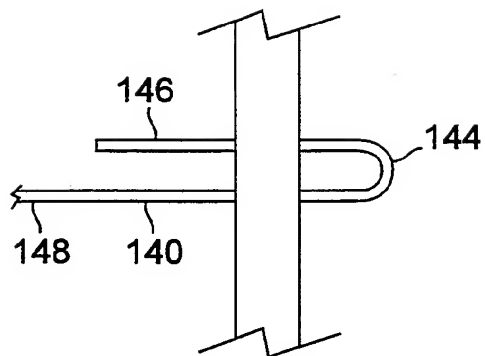
**FIG. 3**



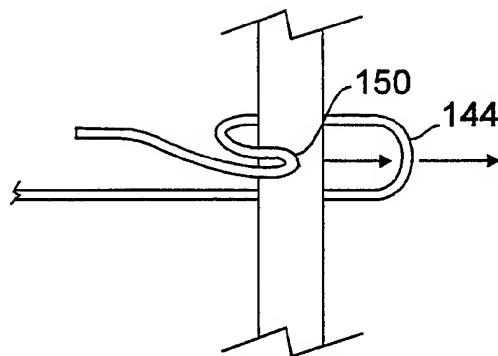
**FIG. 5**



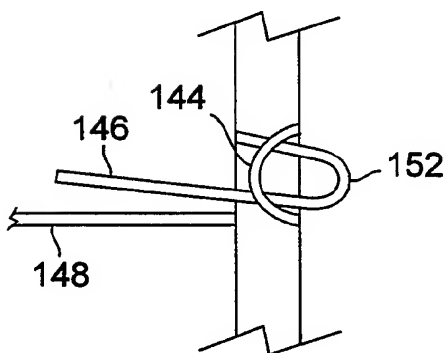
4/12



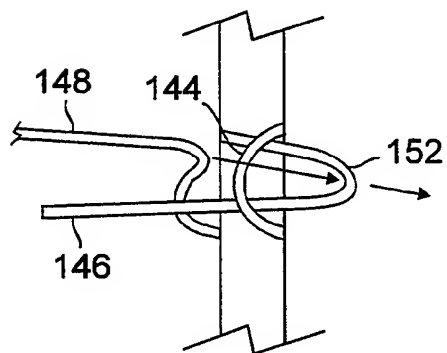
**FIG. 9A**



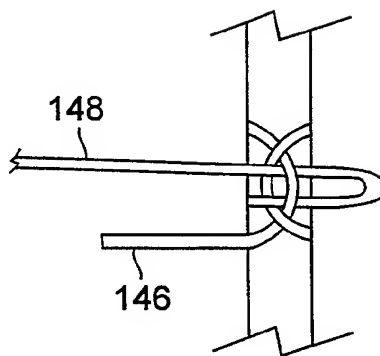
**FIG. 9B**



**FIG. 9C**



**FIG. 9D**



**FIG. 9E**

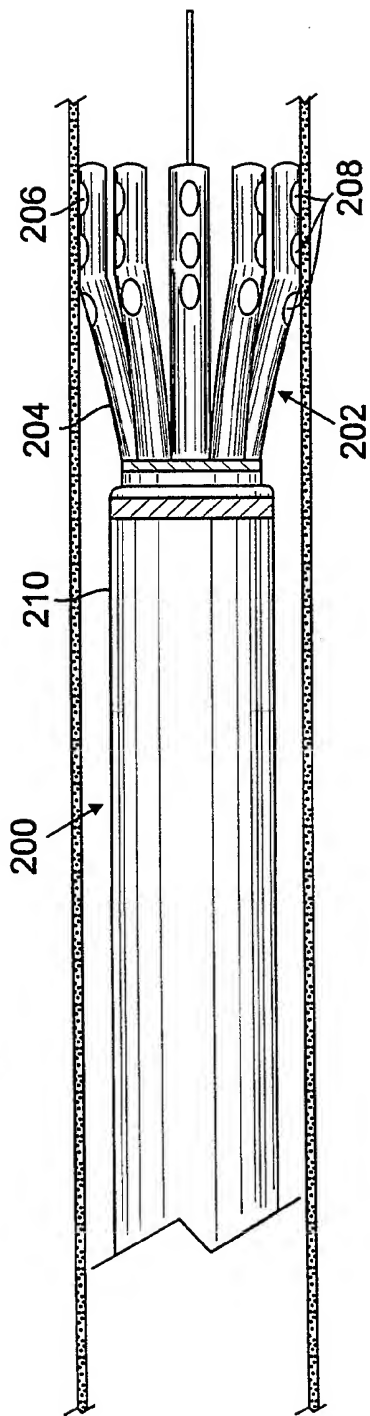


FIG. 10

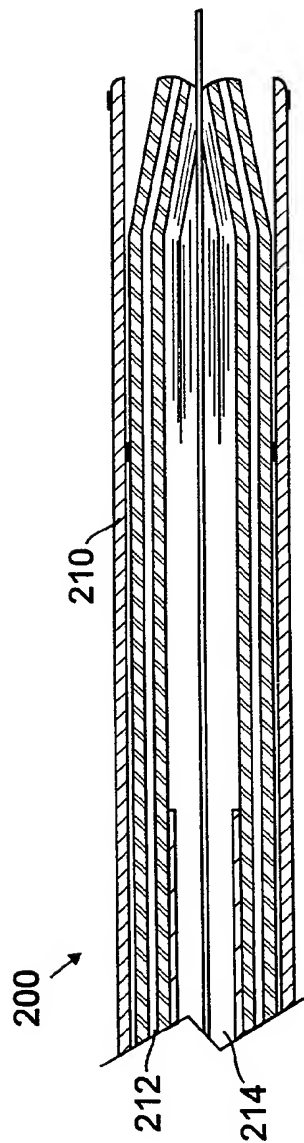
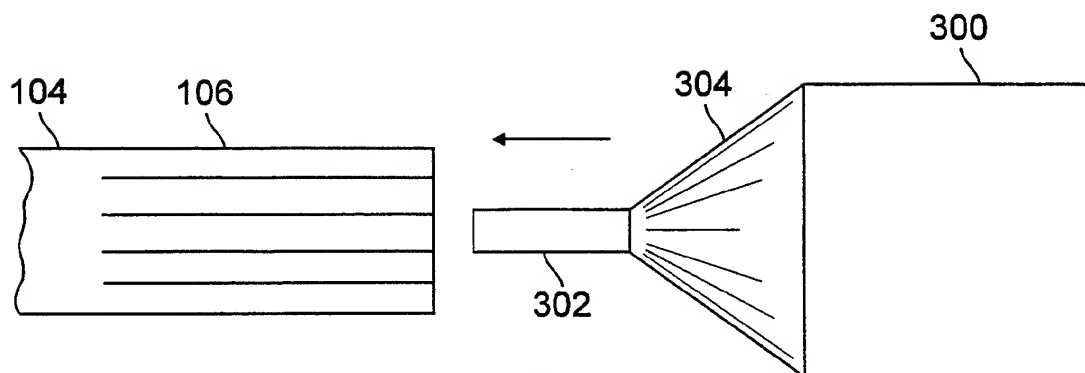
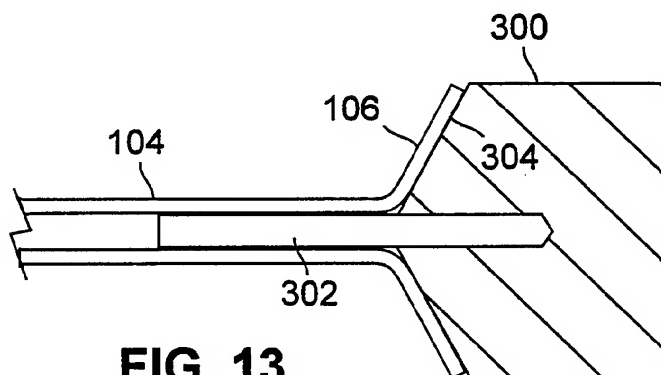
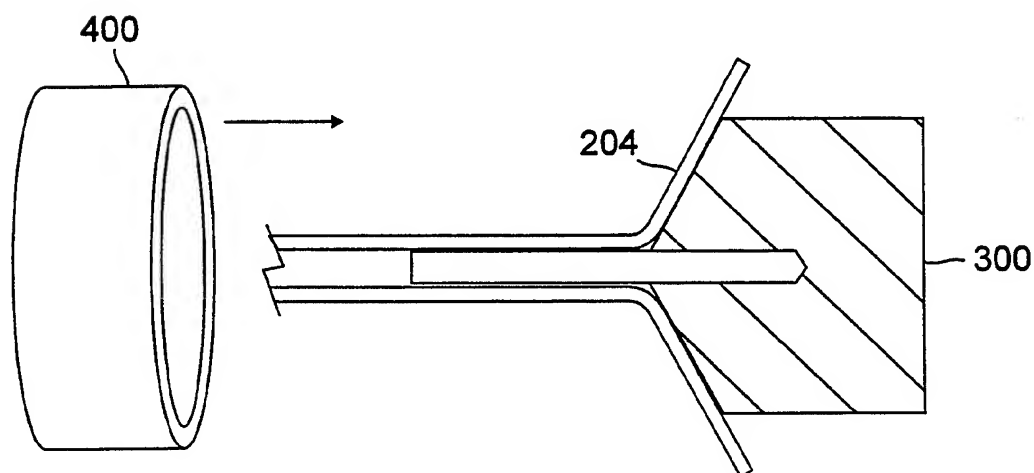
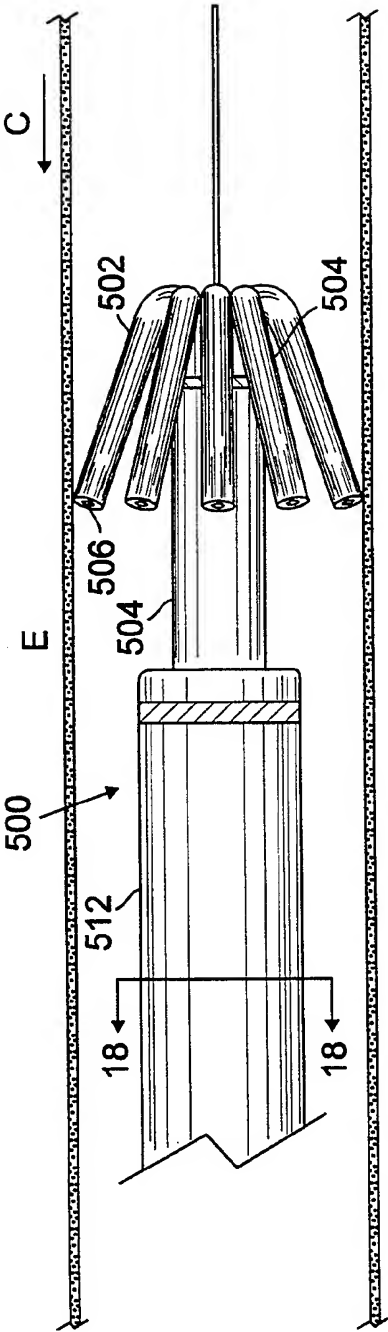
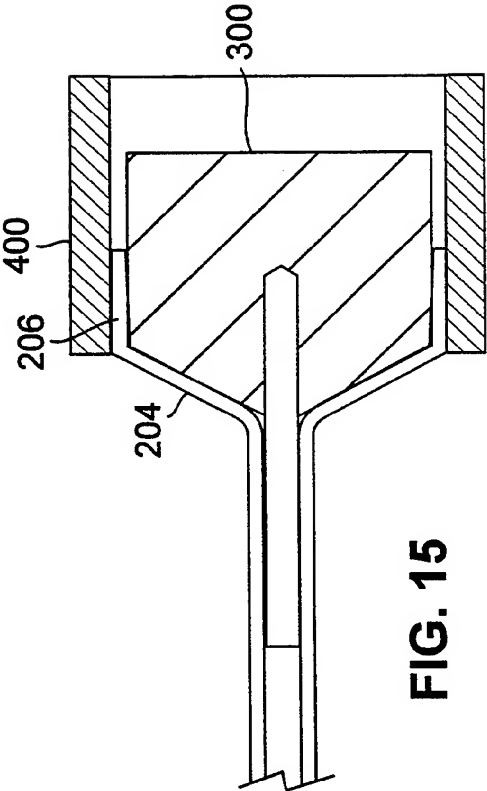


FIG. 11

6/12

**FIG. 12****FIG. 13****FIG. 14**





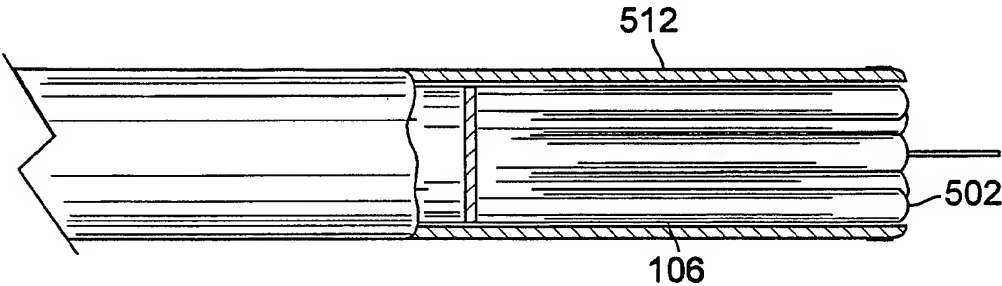
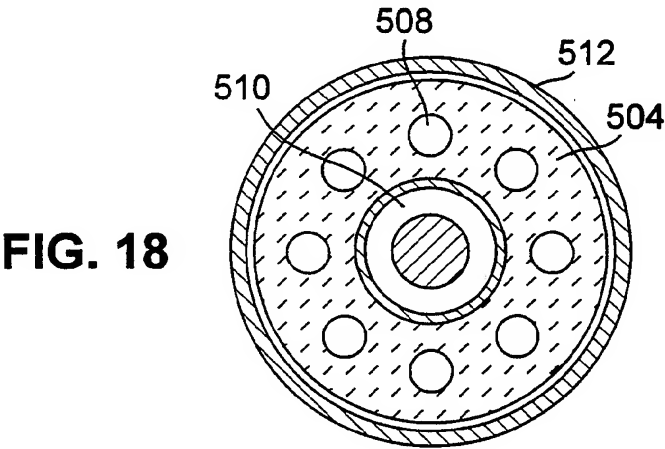
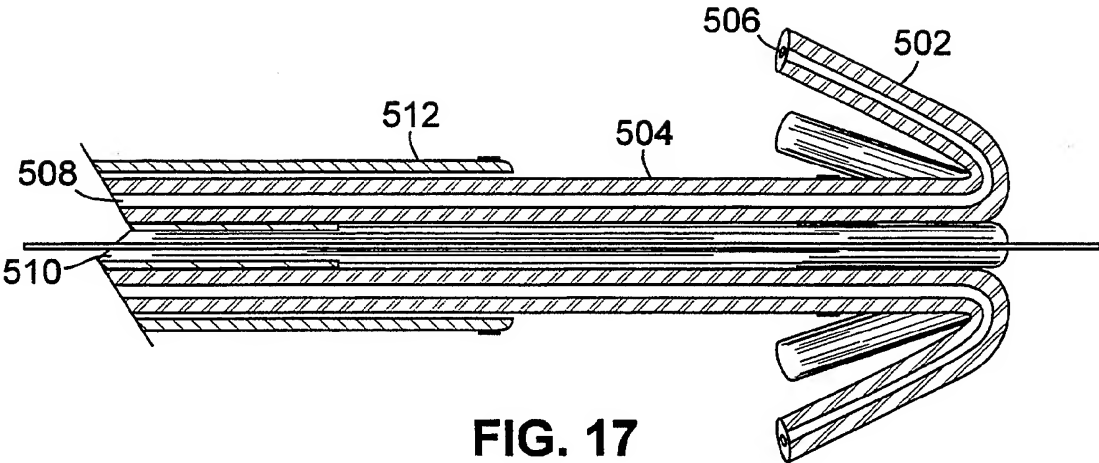
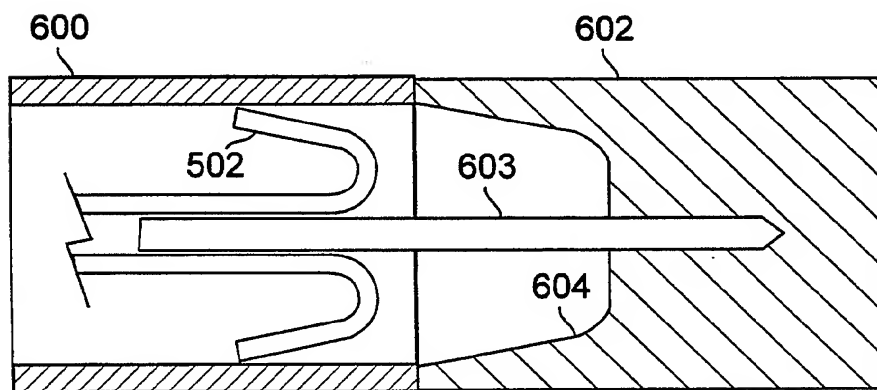
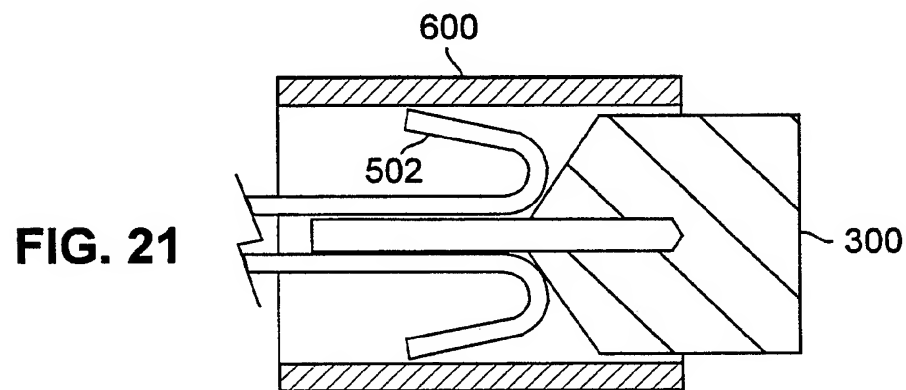
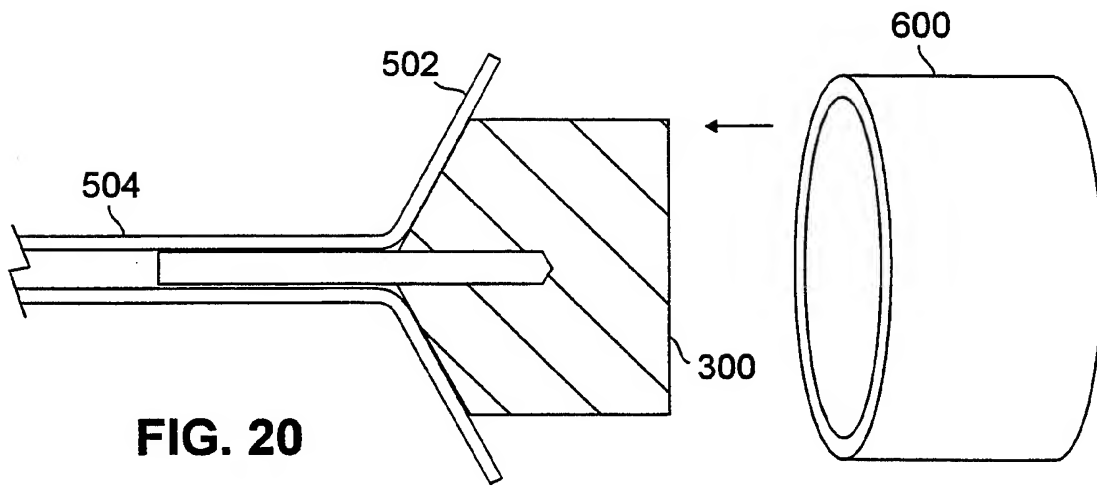


FIG. 19

9/12



10/12

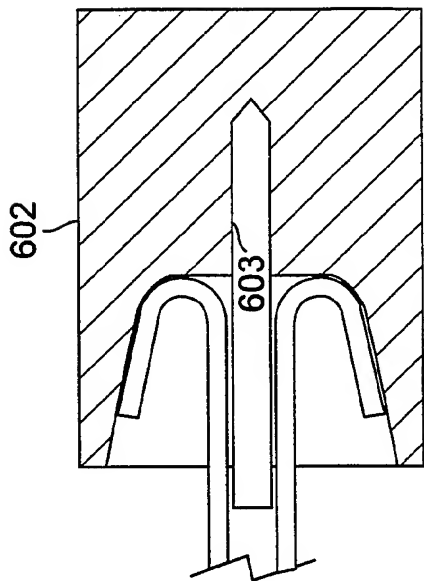


FIG. 23

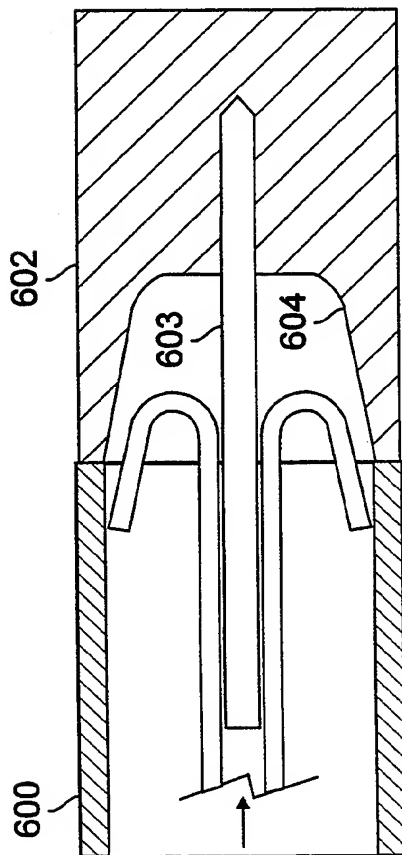


FIG. 22B

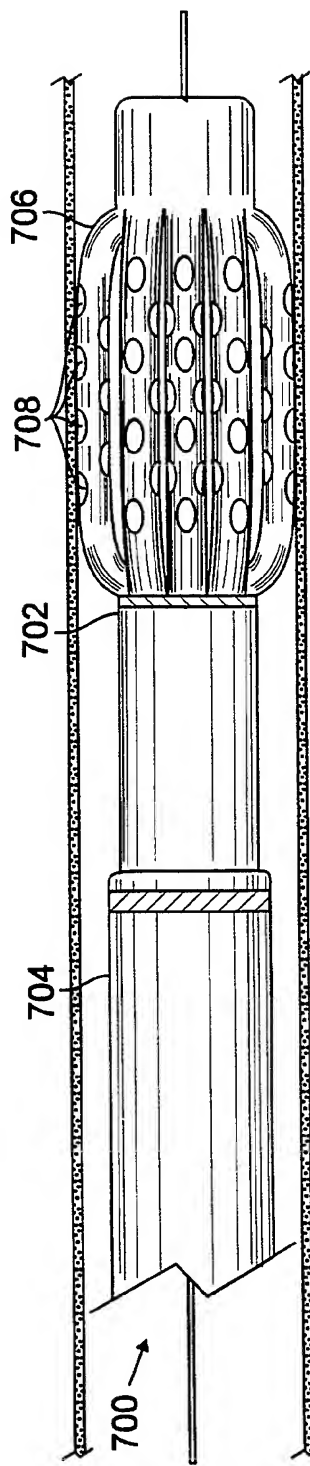


FIG. 24

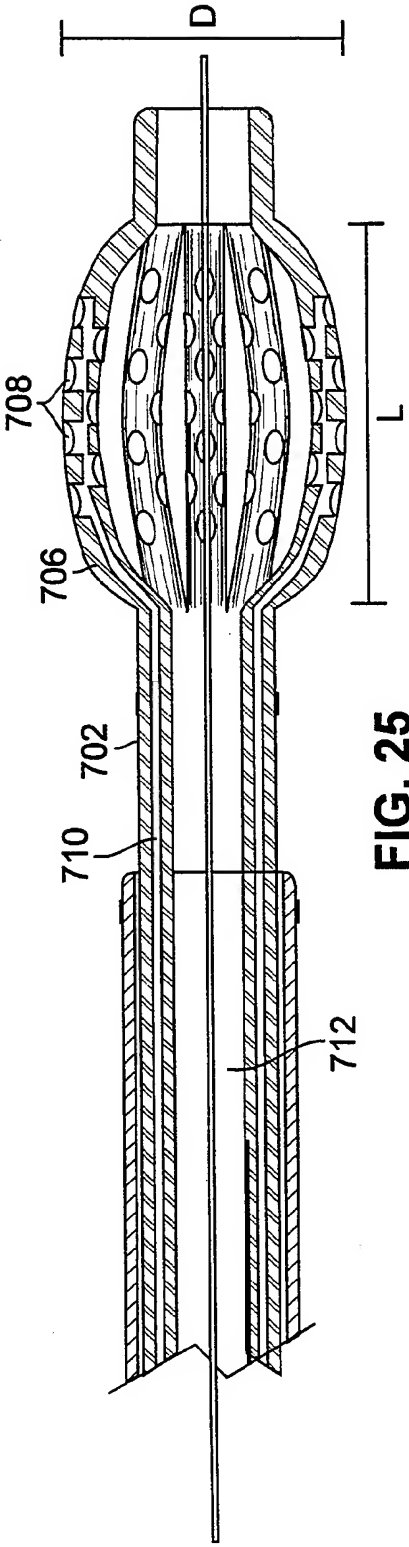


FIG. 25

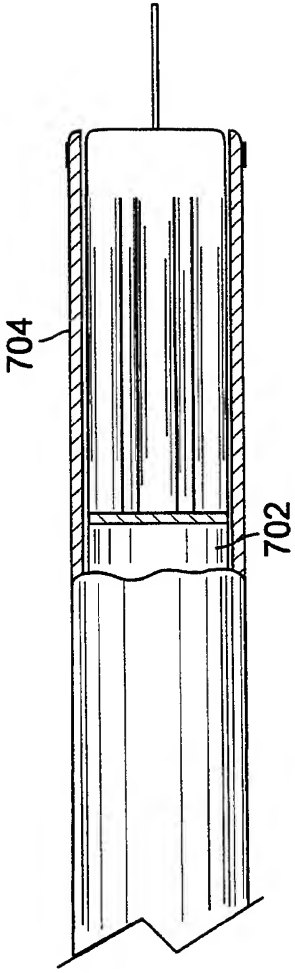
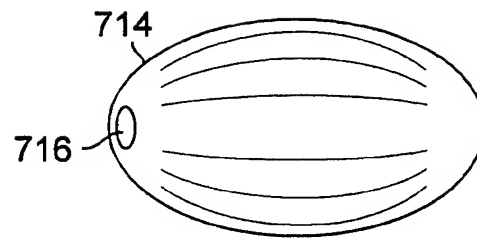
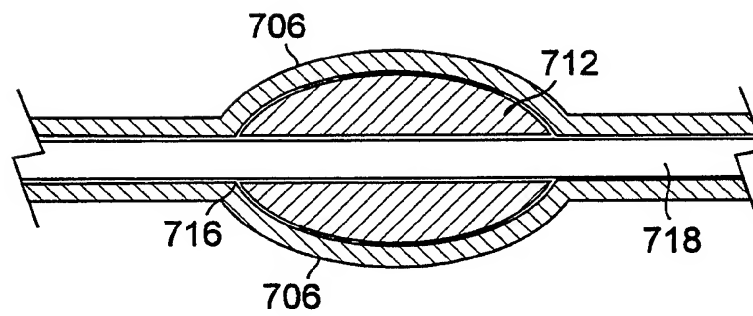


FIG. 26

12/12



**FIG. 27**



**FIG. 28**

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US96/08861

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) :A61M 5/00, 25/00, 31/00

US CL :604/53, 264

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/19, 27, 28, 48, 49, 52, 53, 93, 96, 104-107, 158, 161, 174, 175, 264, 280; 606/191, 194, 198, 200

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---, P Y	US, A, 5,509,900 (KIRKMAN) 23 April 1996, see Figs. 22-24, 29 and 37, and column 7 lines 13-27.	1-11, 35-43, 47 ----- 11-34, 37, 44-46, 52
X --- Y	US, A, 4,873,978 (GINSBURG) 17 October 1989, see entire document.	51 ----- 44, 45, 52
X --- Y	US, A, 5,279,565 (KLEIN ET AL.) 18 January 1994, see entire document.	38, 41 ----- 12-34

☒ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"G" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

20 SEPTEMBER 1996

Date of mailing of the international search report

02 OCT 1996

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RONALD K. STRIGHT, JR.

Telephone No. (703) 308-2113

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US96/08861

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,878,893 (CHIN) 07 November 1989, see entire document especially column 5 lines 1-6.	46
X	US, A, 5,304,120 (CRANDELL ET AL.) 19 April 1994.	35, 38, 39, 41, 42
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A		1-34, 36, 37